

## ***Remarks***

### ***I. Status of Claims***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 28, 29, 31-42, 44-50, and 52-59 are pending in the application, with claims 29 and 50 being the independent claims. Claims 29, 31-35, 42, 50, and 58 are amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

The Examiner noted on page 2 of the Office Action that claims 28, 31, 33-35, 42-47, 50-57, and 59 have been withdrawn as allegedly being drawn to non-elected subject matter. It is respectfully believed that at least claims 33, 42-47, and 50-57 fall within the subject matter of Group I, set out by the Examiner in the Restriction Requirement issued on January 30, 2006, and elected by Applicants<sup>1</sup>. Furthermore, claims 31, 34, and 35 as amended are believed to fall within the subject matter of Group I. Accordingly, Applicants respectfully request that at least claims 31, 33-35, 42-47, and 50-57 be rejoined and examined. Should the Examiner disagree, clarification of why these claims were withdrawn from consideration is respectfully requested.

### ***II. The Amendments***

Support for the amendments to the claims are found throughout the specification as filed. In particular, support for claims 29, 31, and 32 is found at page 11, line 27 to page 12, line 24 and Example 11. Support for claims 33, 34, and 35 is found at page 11,

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<sup>1</sup> The *Chlamydia* insert in plasmid pJJ36-J from *E.coli* TOP10 corresponds to amino acids 29-533 of SEQ ID NO: 2 and the *Chlamydia* insert in plasmid pAH342 from *E.coli* BL21 corresponds to amino acids 29-1012 of SEQ ID NO: 2.

line 27 to page 12, line 24, Example 11, Example 8, and page 6, lines 1-17. Support for claims 42 and 50 is found at page 11, line 27 to page 12, line 24.

By the foregoing amendments, claims 1-27, 30, 43, and 51 are canceled without prejudice to or disclaimer of the subject matter therein. Applicants reserve rights to pursue the canceled subject matter in related patent applications.

### ***III. The Rejections***

#### ***A. The New Matter Rejection of Claims 29, 33, 36-41, and 58 Under 35 U.S.C. § 112, First Paragraph, is Traversed.***

The Examiner rejected claims 29, 33, 36-41, and 58, asserting that "[t]he limitation 'antibody binding to a polypeptide consisting essentially of an amino acid sequence at least 95% identical to amino acids 29-1012 of SEQ ID NO: 2' has no clear support in the specification and the claims as originally filed." Office Action at pages 2-3. Applicants respectfully disagree.

However, solely to facilitate prosecution of this application and not in acquiescence to the Examiner's rejection, Applicants amended the claims to be drawn specifically to an isolated antibody or antigen binding fragment thereof specifically binding to a polypeptide that consists essentially of amino acids 29-1012 of SEQ ID NO: 2. In view of the amendments, the rejection under 35 U.S.C. § 112, first paragraph, is rendered moot. Applicants respectfully request that the rejection be reconsidered and withdrawn.

***B. The Written Description Rejection of Claims 29, 33, 36-41, and 58 Under 35 U.S.C. § 112, First Paragraph, is Traversed.***

The Examiner rejected claims 29, 33, 36-41, and 58 under 35 U.S.C. § 112, first paragraph, alleging that the specification provides no support and fails to describe a representative number of species in a genus and structural features common to the members of the genus. *See* Office Action at page 5. In particular, the Examiner alleged that the specification does not describe an antibody or antigen binding fragment thereof that specifically binds to an amino acid sequence at least 95% identical to amino acids 29-1012 of SEQ ID NO: 2. *See id.* The Examiner also asserted that the specification fails to disclose an antibody or antigen binding fragment thereof that specifically binds to a fragment of SEQ ID NO: 2. *See* Office Action at page 6. The Examiner, however, acknowledged that "the specification discloses a single isolated antibody or antigen binding fragment thereof or antiserum which specifically bind to the polypeptide consisting of amino acid sequence set forth as SEQ ID NO: 2." Office Action at page 5.

Applicants respectfully disagree with this rejection. However, to expedite prosecution of the present application and not in acquiescence to the Examiner's rejection, Applicants amended claims 29, 31-35, 42, 50, and 58 to an antibody that binds to the specified polypeptide. Claims 30, 43, and 51 have been canceled without prejudice or disclaimer. Upon the foregoing amendments, the written description rejection under 35 U.S.C. §112, first paragraph, is rendered moot.

Applicants respectfully point out that the antibody or antigen binding fragment thereof that specifically binds to a polypeptide consisting essentially of amino acids 29-1012 of SEQ ID NO: 2 may additionally cross-react with related polypeptides in

different serotypes of *C. trachomatis* or even different species of *Chlamydia*. For example, the specification notes in Example 11 that antibodies in hyperimmune sera raised against the HMW protein of *C. trachomatis* serotypes L<sub>2</sub> cross-reacted with the corresponding protein in *C. trachomatis* serotypes B, F, and MoPn and *C. pneumoniae*. Therefore, the specification clearly supports that the antibody or antigen-binding fragment thereof that specifically binds to SEQ ID NO: 2 can also specifically bind to related polypeptides, *e.g.*, SEQ ID NOs: 15 and 16.

In view of the amendments and arguments, Applicants respectfully request that the written description rejection under 35 U.S.C. §112, first Paragraph, be reconsidered and withdrawn.

***C. The Enablement Rejection of Claims 29, 33, 36-41, and 58 Under 35 U.S.C. § 112, First Paragraph is Traversed.***

The Examiner has also rejected claims 29, 33, 36-41, and 58 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabling for antibodies or monoclonal antibodies that specifically bind to the variants of the polypeptide disclosed in the application. The Examiner, however, acknowledged that the specification enabled for "[an] isolated antibody or antigen binding fragment thereof or antiserum which specifically bind to the polypeptide consisting of amino acid sequence set forth as SEQ ID NO: 2."

Applicants respectfully disagree with the rejection. However, in order to expedite the prosecution of the present application and not in acquiescence of the Examiner's rejection, Applicants amended claims 29, 42, 50, and 58 to be drawn specifically to SEQ

ID NO: 1 or SEQ ID NO: 2, which is acknowledged by the Examiner to be enabled. Applicants also amended claims 31-35 to be directed to specific polypeptides in addition to SEQ ID NO: 2. Claims 30, 43, and 51 have been canceled without prejudice or disclaimer of the subject matter. In view of the foregoing amendments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

***D. The Art Rejection of Claims 29, 36, 37, and 58 under 35 U.S.C. § 102(e) is Traversed.***

The Examiner rejected claims 29, 36, 37, and 58 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,565,856 ("Skeiky"), filed July 20, 2000 and issued May 20, 2003. In particular, the Examiner alleged that Skeiky discloses "an isolated antibody ... that specifically binds to a polypeptide consisting essentially of an amino acid sequence of at least 95% identical to amino acids 29-1012 of SEQ ID NO: 2." The Examiner compared 29-1012 of SEQ ID NO: 2 of the present application with SEQ ID NO: 190 of Skeiky, alleging that the sequence similarity of the two sequences is 99.7%.

Applicants respectfully disagree. Applicants point out to the Examiner that Skeiky is not prior art under 35 U.S.C. § 102(e). 35 U.S.C. § 102(e) states:

A person shall be entitled to a patent unless ... (e) the invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language ....

(emphasis added).

Applicants point out that the priority date of the present invention predates the filing date of Skeiky. The subject matter of the present invention claims priority to U.S. Application Serial No. 08/942,596, filed on **October 02, 1997**, while Skeiky was filed July 20, 2000, more than three years after the priority date of the present application. While Skeiky was filed as a continuation-in-part application of an application that claims priority to U.S. Application Serial No. 09/208,277, now U.S. Patent No. 6,166,177 ("Probst"), Probst not only has a later filing date, *i.e.*, December 8, 1998, than the priority date of the present invention, but also fails to disclose the corresponding sequence disclosed in Skeiky. Thus, neither Skeiky nor Probst is prior art under 35 U.S.C. §102(e).

Therefore, Applicants respectfully request that the Examiner's rejection of the present application under 35 U.S.C. §102(e) be reconsidered and withdrawn.


***Conclusion***

All of the stated grounds of rejections have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
Elizabeth J. Haanes, Ph.D.  
Attorney for Applicants  
Registration No. 42,613

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1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600  
667143\_1.doc